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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,649

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EXAMINER

PENG, KUO LIANG

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,649	Applicant(s) SEIFALIAN ET AL.	
	Examiner Kuo-Liang Peng	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/6/09 Amendment.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,39 and 41-77 is/are pending in the application.
- 4a) Of the above claim(s) 50-57, 77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38,39,41-49,58-65 and 67-76 is/are rejected.
- 7) ☒ Claim(s) 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Applicants' amendment filed November 6, 2009 is acknowledged. Claims 1-37 and 40 are deleted. Claims 38, 41, 50-57, 65-69 and 74 are amended. Claim 77 is added.
2. Claim objection(s) in the previous Office Action (Paper No. 20090518) is/are removed.
3. Claim rejection(s) under 35 USC 112 in the previous Office Action (Paper No. 20090518) is/are removed.
4. The text of those sections of Title 35, U.S. code not included in this action can be found in prior Office Action(s).
5. The following numbers of pages, paragraphs and/or lines referring to Applicants' Remarks are based on the Amendment filed October 27, 2009; while those of lines referring to the claims based on the Amendment filed November 6, 2009.

6. In response to Applicants' argument regarding the election/restriction (Remarks, page 13), Examiner notes that by virtue of the amendment, the species election requirement on the species set forth in Claim 77 and dependent claims thereof is still applicable. Notably, the amended Claim 38 still constitutes a **generic claim**, which does **not** contain patentable subject matter, *infra*. Therefore, Claims 50-57 and 77 are withdrawn to non-elected species. **However, Applicants are advised that in Claim 54, the substituent "R" is not defined. In Claims 77 and 53, the term "analogue" is indefinite.** Now, Claims 38-39, 41-49 and 58-76 are pending for consideration.

Claim Rejections - 35 USC § 102 and 103

7. Rejection of Claims 38-39, 41-43, 47-48, 59-63, 65, 69 and 73-74 under 35 USC 102(b) as being anticipated by Hanada (EP 324 946) is maintained because the rejection is adequately set forth in paragraph 5 of Paper No. 20090518. Applicant's arguments have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below.

For Applicants' argument (Remarks, page 14, 2nd paragraph), Examiner notes that the subscripts "l" and "m" in Hanada's formulae (1) and (2) can be 0.

For Applicants' argument (Remarks, page 14, 3rd paragraph), Examiner disagrees. First, it is well settled that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993) Second, the prior art anticipates the claimed invention, *supra*. Third, Hanada's disclosure includes siloxane polyol components represented by formulae (1) and (2) where subscripts "l" and "m" are 0.

8. Rejection of Claims 38-39, 41-48, 49, 58-60, 63, 65, 67-71 and 73-76 under 35 USC 103(a) as being unpatentable over Sahatjian (US 2005 0010275).

Sahatjian discloses a polyurethane as set forth in paragraphs 6 and 10 of previous Office action (Paper No. 20090518), which is incorporated herein by reference. Sahatjian further teaches that the number of siloxane segments and that of polyol segments can be equal. ([0131]) Sahatjian is

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silent on more polyol segments with respect to the siloxane segments.

However, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties.

Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)

9. Claim 64 is rejected as being unpatentable over Sahatjian in view of Pinchuk (US 4 739 013).

Sahatjian discloses a polyurethane, *supra*, which is incorporated herein by reference. Though Sahatjian does not teach the copolymer which comprises as component (b) one or more polycarbonate segment(s) of the instant claim, Sahatjian further teaches examples of the polyol of the invention to include polycaprolactone [0085]. Pinchuk teaches polyurethanes formed by reacting -OH or hydroxyl group of a macroglycol component with an -NCO or isocyanate group of a diisocyanate and silanol terminated siloxane (col.3, lines 5-12 and col.4, lines 41-55). Pinchuk further teaches the macroglycols of the invention to include polycarbonate and polyester, such as polycaprolactone or polyacrylate

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(col.3, lines 45-51). Since polycarbonate and polyester, such as polycaprolactone, are known equivalents in the art - as taught by Pinchuk - motivated by the desire to generate polyurethanes with optimal properties, it would have been obvious to one of ordinary skill in the art to have incorporated one or more polycarbonate of Pinchuk into the composition of Sahatjian.

10. Clams 38 and 70-72 are rejected as being unpatentable over Pinchuk in view of Sahatjian.

Pinchuk teaches polyurethanes formed by reacting -OH or hydroxyl group of a macroglycol component with an -NCO or isocyanate group of a diisocyanate and silanol terminated siloxane (col.3, lines 5-12 and col.4, lines 41-55). Pinchuk further teaches that the polyurethane materials of the invention are suitable for vascular grafts (col.2, lines 3-10).

Pinchuk does not teach the copolymer of the instant claim 38 and/or the molded article and/or the implantable device of the instant claim.

Sahatjian teaches polyurethanes made by reacting (A) a polyol, (B) a dihydroxyl-terminated POSS and (C) a diisocyanate [0085]. Sahatjian further teaches the dihydroxyl-terminated POSS of the invention to include

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the structures of [0086] and [0087] and exemplifies the polyurethane with the structure of [0131]. Sahatjian further teaches that the polymer of the invention has a melt or glass transition temperature above body temperature and exhibits an approximate plateau in a plot of storage modulus as a function of temperature at melt or glass transition [0013]. Since both compositions of the invention of Sahatjian and Pinchuk are similar, motivated by the melt or glass transition temperature of the polymer of Sahatjian, it would have been obvious to one of ordinary skill in the art to have formed the vascular graft of Pinchuk utilizing any of the polymer, including the polyurethane, of Sahatjian.

For Applicants' argument (Remarks, page 15, 2nd paragraph and 4th paragraph to page 16, 2nd paragraph), Examiner's position is set forth in paragraph 8 above.

For Applicants' argument (Remarks, page 15, 3rd paragraph), with respect to the limitation of the **presence** of a silsesquioxane-containing group, Examiner notes that a genus does not always anticipate a claim to a species within the genus. However, when the species (i.e., the silsesquioxane-containing chain extender) is clearly named, the species claim is anticipated no matter how many other species are additionally

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named. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter.

1990)(Emphasis added)

11. The affidavit filed October 27, 2010 has been thoroughly considered. However, it is not persuasive because of Examiner's positions set forth in the responses to Applicants' arguments, *supra*.

12. Claim 66 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the

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THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (571) 272-1091. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jim Seidleck, can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

klp
March 15, 2010

/Kuo-Liang Peng/
Primary Examiner, Art Unit 1796